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Evaluation of Commercial IV Pressure Infusors

Patricia M. Dubill, John W. Hodge,
Thomas P. Greene, and Glenn E. Toms

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Final Report

U S ARMY BIOMEDICAL RESEARCH & DEVELOPMENT LABORATORY
Fort Detrick
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Rapid fluid resuscitation of hypovolemic casualties is necessary to prevent organ failure and death. Greater flow rates than can be achieved with gravity flow using conventional IV sets and large catheters is obtainable by two methods: use of large bore, multiple spike, rapid infusion sets, and use of pressure infusion devices. The latter are more desirable for the field because of their lack of dependence on gravity for operation. Ten commercially available pressure infusors were evaluated for their field applicability. Results (using lactated Ringer's) indicated a problem with pressure decay for inflatable bladder type infusors, which when used with a 14 gauge catheter emptied in 2-3.5 minutes (500 cc size) and 3.5-11.5 minutes (1000 cc size). In contrast, the one spring-activated type model studied ("Biomed Spring Activated Infusion Pressor," Migada, Inc.) emptied a 500 cc bag in under 1 minute and was found previously (Swenson, 1986) to empty a 1000 cc bag in under 4 minutes. Additional features such as durability, compactness, unlimited shelf life and IV bag protection associated with the Migada product make it the recommended pressure infusor for field asanguineous fluid administration.

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Evaluation of Commercial IV Pressure Infusors

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ABSTRACT

Rapid fluid resuscitation of hypovolemic casualties is necessary to prevent organ failure and death. Greater flow rates than can be achieved with gravity flow using conventional IV sets and large catheters is obtainable by two methods: use of large bore, multiple spike, rapid infusion sets, and use of pressure infusion devices. The latter are more desirable for the field because of their lack of dependence on gravity for operation. Ten commercially available pressure infusors were evaluated for their field applicability. Results (using lactated Ringer's) indicated a problem with pressure decay for inflatable bladder type infusors, which when used with a 14 gauge catheter emptied in 2 - 3.5 minutes (500 cc size) and 3.5 - 11.5 minutes (1000 cc size). In contrast, the one spring-activated type model studied ("Biomed Spring Activated Infusion Pressor," Migada, Inc.) emptied a 500 cc bag in under 1 minute, and was found previously (Swenson, 1986) to empty a 1000 cc bag in under 4 minutes. Additional features such as durability, compactness, unlimited shelf life and IV bag protection associated with the Migada product make it the recommended pressure infusor for field asanguineous fluid administration.

INTRODUCTION

"Acute hemorrhage is the major cause of death during conventional land warfare . . . . Fifty percent of all soldiers 'killed-in-action' exsanguinate prior to reaching a fixed medical treatment facility" (Maningus, 1987). Loss of intravascular circulating volume is the primary problem, and must be treated by early rapid fluid resuscitation to prevent organ failure and death. Blood is the most important fluid in the treatment of hemorrhagic shock (Baxt, 1985), but is unavailable in the prehospital care scenario. Even in fixed facilities, blood of the correct type may be unavailable, and is preferably not administered until blood typing and crossmatching has been performed. Fortunately, a variety of asanguineous fluids, such as lactated Ringer's[1], are available to at least temporarily restore hemodynamic stability of trauma patients until blood becomes available.

The recommended treatment protocol for severe hemorrhagic shock is administration of 2 liters of lactated Ringer's as rapidly as possible, followed by reassessment of the patient's clinical condition (Edlich, 1985). Use of large catheters, preferably 14 or 16 gauge, at two or more infusion sites is advocated (Mattox, 1988). Smaller 18 gauge needles may be used if insertion of a larger catheter is too difficult and time-consuming, which is often the case in severely hypovolemic patients. Although the maximum flow

[1]A balanced salt solution containing sodium, potassium, chloride, and lactate at a pH of 6.5 (Baxt, 1985).

through these smaller catheters is less than for the larger catheters, it can be increased marginally with the incorporation of a sheath/dilator device.

Even with the use of multiple intravenous (IV) lines and large catheters or dilators, the maximum achievable flow rates when using conventional IV sets relying on gravity flow are suboptimal. Large bore infusion sets and pressure infusion devices have been developed to more rapidly infuse stabilizing fluids to trauma patients.

The development of large bore infusion sets has enabled infusion of up to 1600 cubic centimeters (cc) per minute via a single peripheral venipuncture (Fried, 1986). Other rapid infusion sets combine the advantages of large bore tubing with bifurcated or quadruplicated ends (proximal to the catheter connection point) to enable simultaneous administration of fluid from 2 to 4 IV bags through a single line. Although these sets have considerable value in fixed facilities, their reliance on gravity flow for operation limits their application by medics in the field and during transport, where a place to hang IV bags usually is not readily available.

The requirement for gravity flow can be obviated with the use of pressure infusion devices. Intravenous solutions are supplied in flexible containers suitable for external compression by an inflatable bladder system or other mechanism. Use of a compression (pressure infusion) system provides greater flow rates than gravity alone, and eliminates the need for an IV pole. Currently, field medics must fashion an IV pole from a stick or rely on the patient's body weight for compression by placing the bag underneath the patient. Provision of a small, lightweight pressure infusion device would represent a considerable improvement over these methods. An evaluation of commercially available pressure infusion devices was performed to determine which devices are most suitable for combat casualty care.

MATERIALS AND METHODS

A market survey was conducted to identify vendors of pressure infusion devices. Potential vendors were identified from ECRI Health Devices Sourcebook, advertisements in new product announcement magazines, and the Israeli Defense Forces. Devices that relied on compressed gas for operation or that could not be compacted for convenient storage by a medic were excluded from consideration.

The products determined to have potential field application were obtained, weighed and measured (Hodge and Greene, 1988). For each infusor that had a pressure gauge, its accuracy was determined by connecting the infusor gauge to a Dwyer manometer (Dwyer Instruments, Inc., Michigan City, IN) with known performance characteristics. The infusor gauge and manometer were simultaneously pressurized to the working pressure of the infusor and the resulting pressure reading on the Dwyer manometer was recorded. The measurements were replicated twice, and their averages and standard deviations were computed.

Pressure-flow characteristics of the infusors were determined using appropriate bag volume capacities of lactated Ringer's solution in VIAFLEX^R single dose containers (Travenol Laboratories, Inc., Deerfield, Illinois) and a standard IV set with its roller clamp in the full open position, to achieve the maximum flow rates possible (Hodge and Greene, 1988, and Hodge et al., 1988). Because any of the three previously recommended catheter gauge sizes (Mattox, 1988) could be used in the field, tests were conducted for 14, 16, and 18 gauge catheters. A bag of Ringer's lactate was inserted into each infusor and the entire flow system was placed on a level bench. Each infusor was pressurized to its recommended working pressure of 300 millimeters of mercury (mm Hg) and cumulative flow delivered over time was measured in a graduated cylinder at 1 minute intervals, measured with a timer. Pressure on the infusor gauge was also recorded at these intervals. The tests were replicated and the results for time to empty the bags were averaged.

Reliability, availability and maintainability data were not sought because the devices are expendable.

RESULTS

Vendors identified from the market survey are listed in Appendix 1. Ten commercial devices (8 different model types) met inclusion criteria and were evaluated. Two models were available in 500 and 1000 cc sizes, so both sizes were studied. Nine of the ten devices studied used an inflatable bladder compression system and one used a spring activated pressor mechanism. The manufacturer, trade name, bag capacity, size, weight, and type of pressure gauge of each product tested is given in Table 1. Photographs or drawings of the infusors are given in Figures 1 - 6.

Results of the pressure gauge accuracy tests indicated that most infusor

Table 1. Manufacturers and characteristics of commercially available IV pressure infusors.

MANUFACTURER	PRODUCT TRADE NAME	BAG SIZE (cc)	UNIT COST ($)	WEIGHT (kg)	CUBE (in^3)	PRESSURE GAUGE
Abbott Laboratories	"Pressure Administration Cuff"	500	63.25	0.270	101	STANDARD
Baxter Travenol	"Infusor, Pressure, Blood Collecting-Dispensing Bag" (NSN 6515-00-584-2893)	500	39.46	0.174	53	NONE
Biomedical Dynamics	"Infusable"	500 1000	13.50 14.50	0.095 0.096	63 120	PISTON-TYPE
Lifemed Technologies	"Pressure Infusion Cuff"	1000	65.00	0.257	81	STANDARD
Medex	"C-Fusor"	500 1000	74.40 79.60	0.335 0.377	149 279	STANDARD
Migada	a. "Biomed Spring Activated Infusion Pressor"	500-1000	58.00	0.567	52	NONE
	b. "Pressure Infusor"	500	80.00	0.669	198	STANDARD
PA Medical	"Pressure Infusor"	1000	50.50	0.490	198	STANDARD

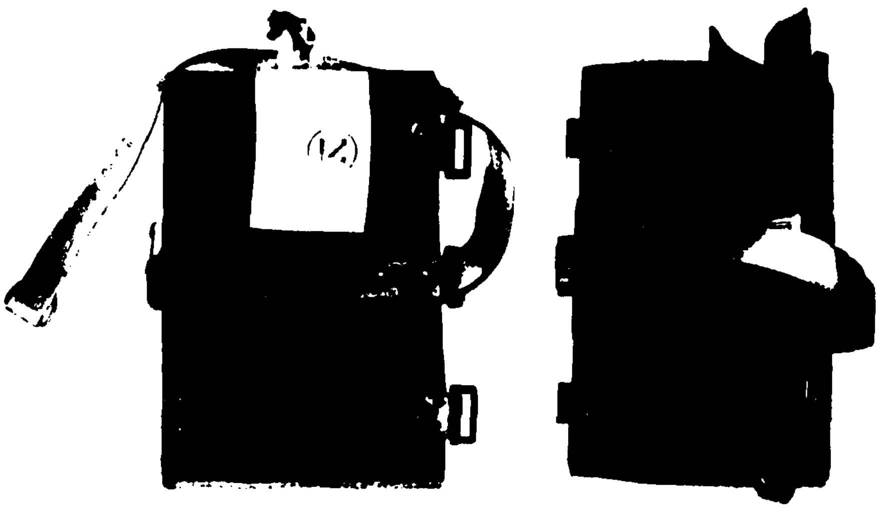

Figure 1. Photograph of Migada "Biomed Spring-Activated Pressure Infusor," 500-1000 cc.

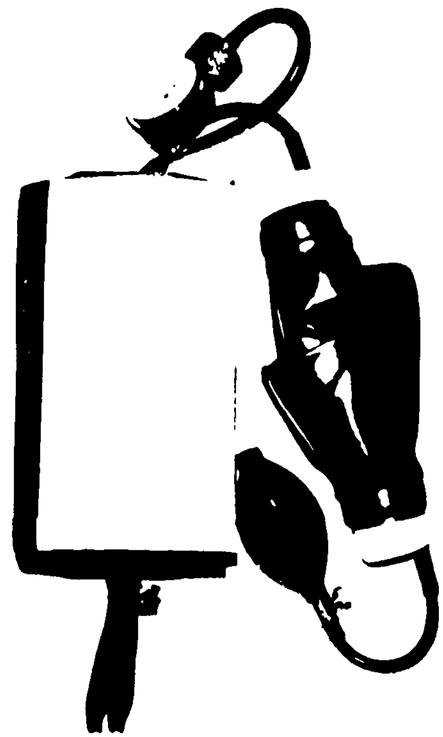

Figure 2. Photograph of Migada "Pressure Infusor," 500 cc.

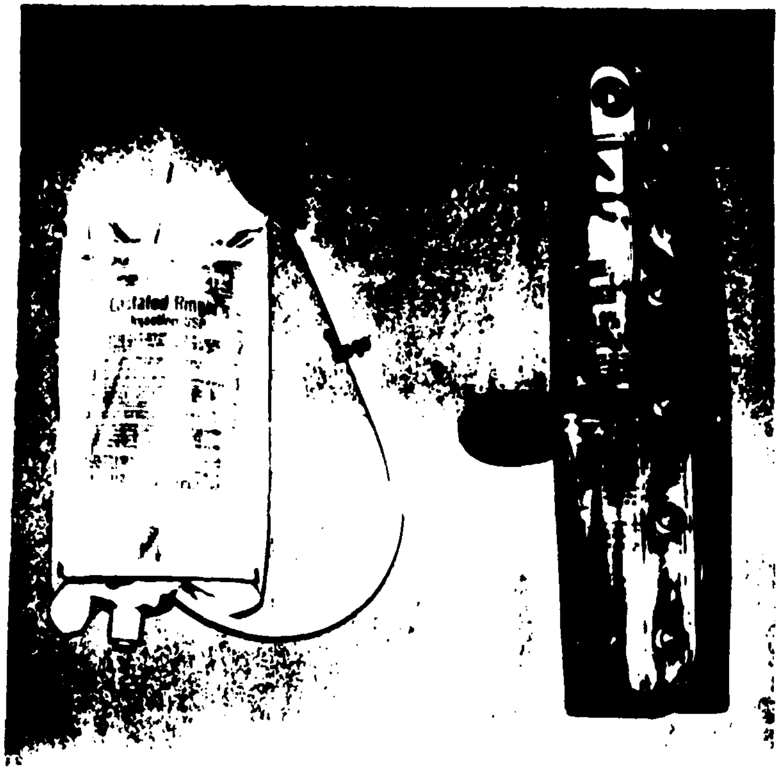

Figure 3. Photograph of Biomedical Dynamics "Pressure Infusion Cuff," 500 cc (left--1000 cc size similar, not shown) and PA Medical "Pressure Infusor," 1000 cc (right).

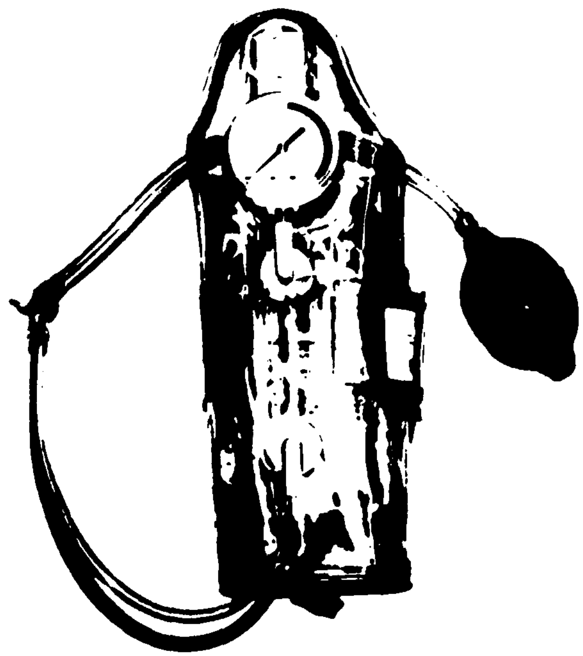

Figure 4. Photograph of Medex "C-Fusor," 500 cc (1000 cc size similar, not shown).

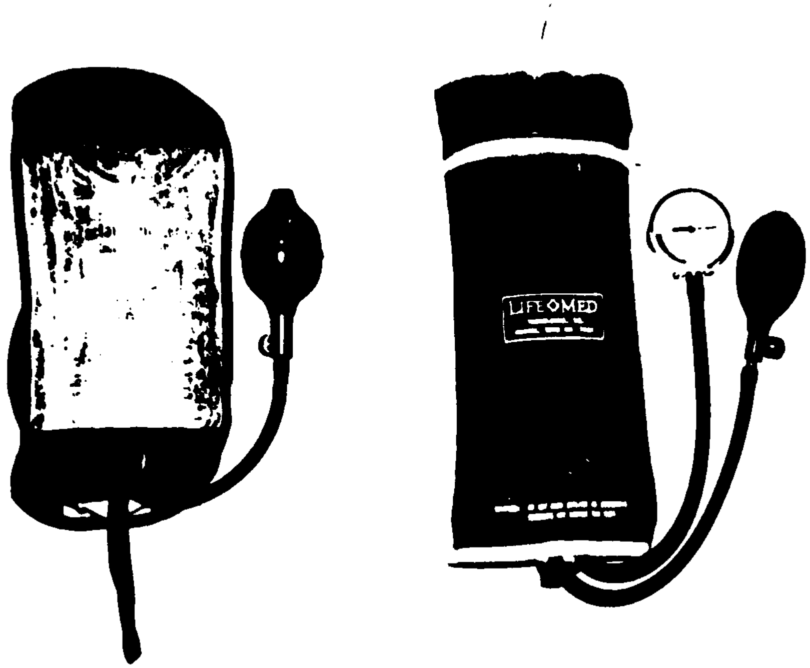

Figure 5. Photograph of Baxter Travenol "Infusor, Pressure, Blood Collecting-Dispensing Bag," 500 cc (left) and Lifemed Technologies "Pressure Infusion Cuff," 1000 cc (right).

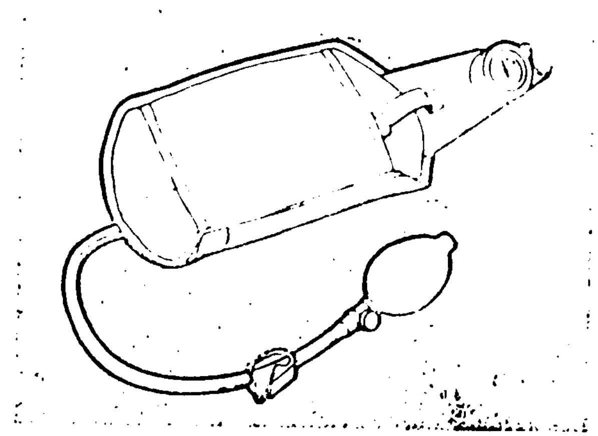

Figure 6. Drawing of Abbott Laboratory "Pressure Administration Cuff" 500 cc.

gauges gave readings within 10 mm Hg of the actual pressure. Three of the infusors were inaccurate, on average, by over 10 mm Hg. These included both bag sizes of the Biomedical Dynamics infusors and the 500 cc size Medex infusor. Data are presented in Table 2.

The results of the pressure-flow studies indicated a problem with pressure decay with the inflatable bladder type infusors, as shown in Figures 7-8; whereas the Migada "Biomed" spring model emptied much more rapidly (500 cc in < 1 minute for all 3 catheter sizes). When used with 1000 cc bags and a 14 gauge catheter, the spring model reportedly empties in less than 4 minutes (Swenson, 1986). In contrast, the time required to empty the bladder types with 500 cc capacities ranged from 2 - 3.5 minutes for the 14 gauge catheter, 2.5 - 4.5 minutes for the 16 gauge catheter, and 5 - 6 minutes for the 18 gauge catheter. The time to empty the bladder types with 1000 cc capacities ranged from 3.5 - 11.5 minutes for the 14 gauge catheter, 5.5 - 15.5 minutes for the 16 gauge catheter, and 12 - 21.5 minutes for the 18 gauge catheter. Performance characteristics of the 500 cc size bladder types were fairly similar; however, for the 1000 cc size, the Medex "C-Fusor" appeared to perform significantly better than the other bladder types, and performed comparable to the Migada "Biomed" spring model.

DISCUSSION

Although the flow rates achieved using pressure infusors were not as high as have been reported using rapid infusion sets (Satiani, 1987 and Millikan et al., 1984), there was still a considerable improvement over the

Table 2. Results of pressure gauge tests on IV pressure infusors for a working pressure of 300 mm Hg.

ID #	INFUSOR	MEAN PRESSURE (mm Hg)	STD DEV
1	Biomed. Dyn. (500 cc)	277	6.4
2	Biomed. Dyn. (1000 cc)	289	1.7
3	Medex (1000 cc)	302	0.0
4	Medex (500 cc)	286	5.1
5	Abbott Labs (500 cc)	305	4.0
6	Baxter Travenol (500 cc)	N/A[a]	
7	Lifemed (1000 cc)	303	1.7
8	PA Medical (1000 cc)	306	1.2
9	Migada--cuff type (500 cc)	295	4.0
10	Migada--spring type (500+ cc)	N/A	

[a]No gauge provided with device

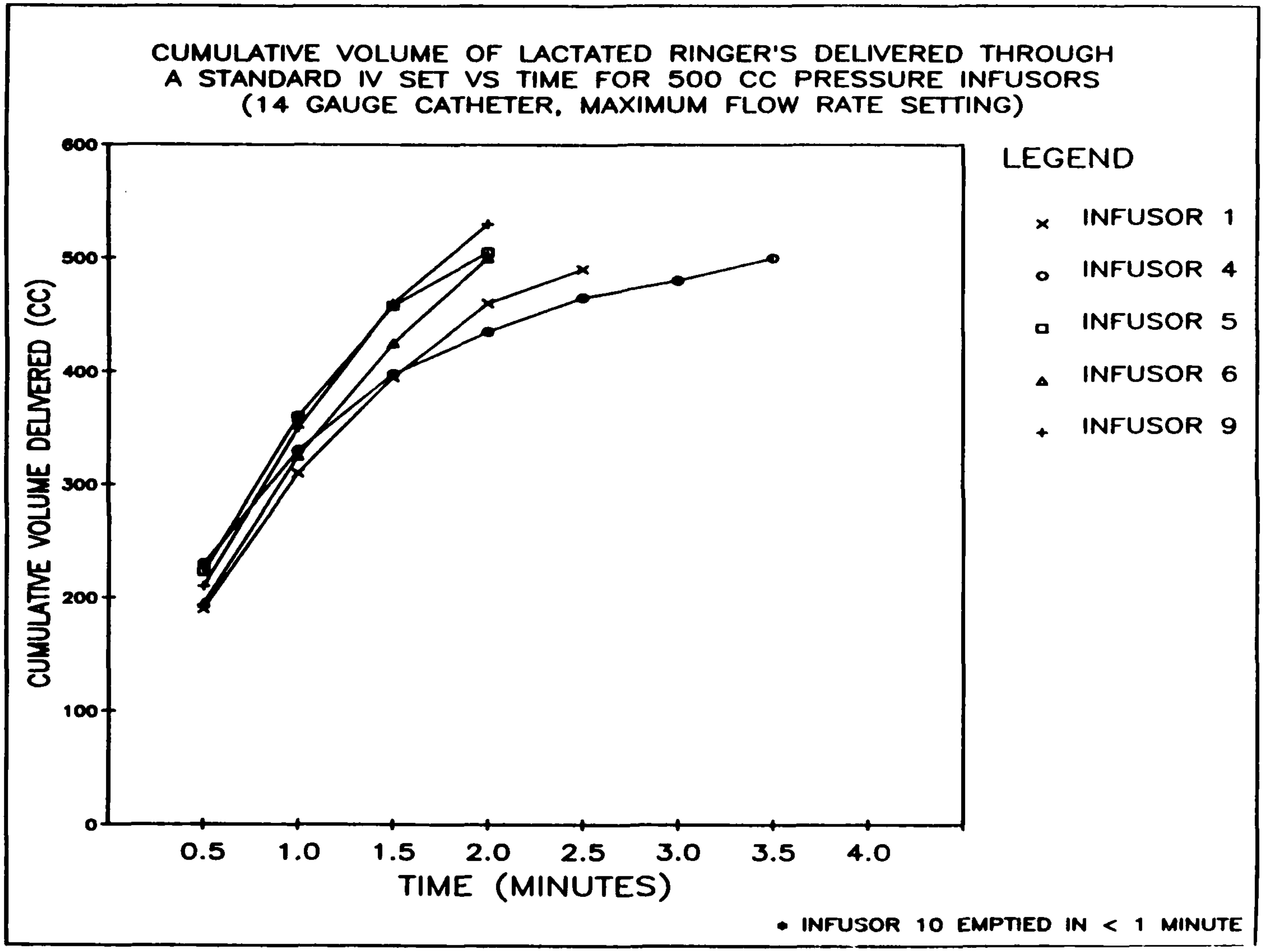

Figure 7. Pressure-flow data for 500 cc size pressure infusors (14 gauge catheter).

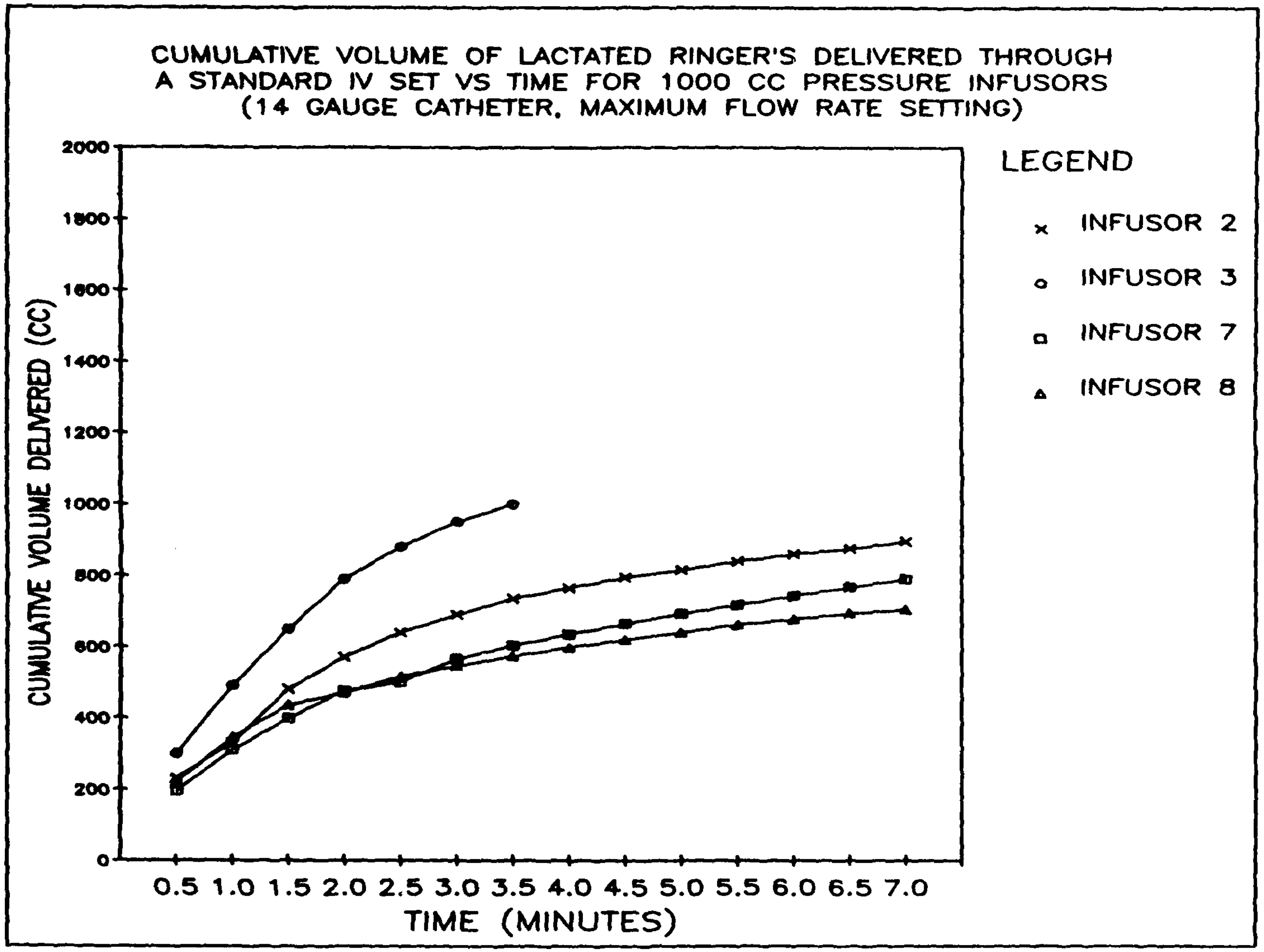

Figure 8. Pressure-flow data for 1000 cc size pressure infusors (14 gauge catheter).

flow obtainable with gravity, even for the 18 gauge catheter. The inaccuracies of several of the pressure gauges are probably not clinically important, although this may explain why some bladder types performed marginally better than others. For example, the two slowest 500 cc infusors, Medex and Biomedical Dynamics (Figure 7), had the lowest pressure readings (Table 2), yet the larger Medex infusor with a higher pressure reading (Table 2) had the best performance of the 1000 cc bladder type infusors. The primary differences are probably due to differences in construction materials, which ranged from fabric to plastic (Cox, 1984).

The problems with pressure decay for the inflatable bladder type devices have been reported previously, when used as intravascular catheter flush devices during invasive blood pressure monitoring (Cox, 1988, Hart, 1984). These problems can only be overcome by periodic recharging (reinflating), which is inefficient in the field. Therefore, the spring infusor appears to be the best choice for rapid field asanguineous fluid administration. Whether this applies to infusion of blood products as well is unknown, because it has not been determined if significant hemolysis occurs with use of the product. Blood has been safely administered with the bladder types, but since the spring infusor produces higher flow rates, and therefore higher shear rates, the safety of the spring model for blood product infusion is unknown[2].

[2]The magnitude of hemolysis is proportional to magnitude of shear stress, which is a function of hematocrit, protein concentration and type of flow (laminar or turbulent), which in turn is a function of velocity, geometry, and fluid properties (Calkins et al., 1982).

In addition to its advantages in pressure-flow characteristics over the inflatable bladder types, the spring infusor offers the following desirable characteristics for field use: 1) unbreakable, 2) unlimited re-use, 3) foldable to 0.6 x 3.1 x 7 inches for convenient storage, 4) usable with all commercially available infusion bags, 5) does not require deflation prior to insertion of a new bag, and 6) protects IV bags from puncture. The only potential problem with it is that considerable force is required to close the infusor around the IV bag. Concerns have been raised regarding the potential for air embolism when using pressure infusors on a level surface with the patient, because of the position of bag port and drip chamber relative to the bag fluid level. This potential hazard can probably be abated with the use of special infusion sets designed to prevent air emboli under these conditions (Biedermann, 1984), including a set that is supplied with the Migada spring infusor.

The importance of applying whatever methods are available to rapidly infuse stabilizing fluids to hypovolemic shock patients cannot be overemphasized. In some circumstances, even when commercial pressure infusors have been unavailable due to limited supply, clinicians reportedly jerry-rigged pressure infusors from empty IV bags (Lawes, 1985). Supply of pressure infusion devices to appropriate field personnel could reduce the morbidity and mortality associated with hypovolemia in battlefield casualties.

CONCLUSIONS AND RECOMMENDATIONS

Of ten commercially available pressure infusors tested, the one with superior field relevant features and pressure-flow characteristics for rapid infusion of asanguineous fluids was the Biomed Spring Activated Infusion Pressor, sold by Migada, Inc. Standardization of this item is recommended.

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Lawes, E. G., "A Disposable Intravenous Pressure Infusion Device," Anesthesiology, 62:93, 1985.

Maningus, Peter A., Product Development: 7.5% NaCl in 6% Dextran 70, IND #2696, Letterman Army Institute of Research, San Francisco, CA, July, 1987.

Mattox, Kenneth L., Moore, Ernest E., and David V. Feliciano, Trauma, Appleton & Lange, Norwalk, CT, 1988.

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Satiani, Bhagwhan, Fried, Steven J., Zeeb, Paul, and Robert E. Falcone, "Normothermic Rapid Volume Replacement in Traumatic Hypovolemia: A Prospective Analysis Using a New Device," Archives of Surgery, 122:1044-7, 1987.

Swenson, Louis, "Evaluation of Israeli Infusion Device," U.S. Army John F. Kennedy Special Warfare Center, Fort Bragg, NC, 6 Mar 1986.

APPENDIX 1. Manufacturers of IV pressure infusion devices and availability of field relevant models.

Abbott Laboratories
Hospital Products Division
Abbott Park, Illinois 60064
(312) 937-60064
AVAIL: 1 Model

Aspen Laboratories, Inc.
Sub Zimmer USA
P.O. Box 3936
Englewood, CO 80155
(800) 431-8522
AVAIL: None

Baxter Travenol
Sub Travenol Laboratories, Inc.
1 Baxter Parkway
Deerfield, IL 60015
(312) 948-2000
AVAIL: 1 Model

Biomedical Dynamics Corp.
11921 Portland Ave.
Burnsville, MN 55337
(800) 328-0164
AVAIL: 1 Model

Kendall-McGaw Laboratories
Div The Kendall Co.
P.O. Box 11887
Santa Ana, CA 92711
(800) 854-6851
AVAIL: Hand-operated Model

Lifemed Technologies, Inc.
8630 Westpark Drive
Houston, TX 77063
(800) 543-3633
AVAIL: 1 Model

Medex, Inc.
3637 Lacon Road
Hilliard, OH 43026
(800) 848-1757
AVAIL: 1 Model

Migada, Inc.
150 East Olive Ave. #215
Burbank, CA 91502
(818) 848-3880
AVAIL: 2 Models

Ohmeda
Div The BOC Group Inc.
P.O. Box 7550
Madison, WI 53707
(800) 345-2700
AVAIL: None

PA Medical Corp.
Rt. 8 Nashville Highway
Columbia, TN 38401
(615) 381-3422
AVAIL: 1 Model

Ritter-Tycos
Div Sybron Corp.
Glenn Bridge Road
Arden, NC 28704
(704) 684-8111
AVAIL: Non-compactable Model

Sorenson Research
Div Abbott Laboratories
4455 Atherton Drive
Salt Lake City, UT 84123
(800) 453-9402
AVAIL: None

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